

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

**REDACTED VERSION**

C.A. No. 13-cv-3288-TPG

**ENDO PHARMACEUTICALS INC'S OPPOSITION TO ROXANE'S  
MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER**

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## I. PRELIMINARY STATEMENT

A year after filing its Answer, Defendant Roxane Laboratories, Inc. (“Roxane”) now seeks to amend it to include express and implied license defenses that were known at the time it filed that Answer and have already been fully considered and rejected by the Federal Circuit Court of Appeals. The Federal Circuit’s holdings leave Roxane with absolutely no daylight to pursue these arguments:

***No Express License:*** “Roxane’s express license arguments are meritless.”

***No Implied License:*** “You get what you bargain for. And we will not use the implied license doctrine to insert ourselves into that bargain and rewrite the contract.”

*Endo Pharms. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1374, 1376, 1379 (Fed. Cir. 2014), *reh’g en banc denied* (Jun. 3, 2014).

Roxane’s only justification for seeking to reopen these fully litigated issues is that it could possibly “develop further evidence” that would change the outcome. But the relevant information was in Roxane’s own possession, and it presumably presented its best evidence at the time of the preliminary injunction. Plaintiff Endo Pharmaceuticals Inc. (“Endo”) has responded to all discovery Roxane has sought, and Roxane cannot point to any particular evidence not before the Federal Circuit that might alter the result. Roxane’s proposed amendments adding express and implied license defenses are therefore entirely futile and Roxane’s motion should be denied with respect to those defenses.

As Endo has previously conveyed to Roxane, it does not dispute Roxane’s proposed amendment insofar as it asserts a new unclean hands defense, and hence, Endo does not oppose Roxane’s motion solely with respect to that defense.

## II. BACKGROUND

This is a patent infringement action concerning Roxane's infringement of three of Endo's patents: U.S. Patent Nos. 7,851,122 (the "'122 Patent"); 8,329,216 ("the '216 patent"); and 7,851,482. Endo filed its Complaint on May 15, 2013, and Roxane answered on July 15, 2013. (D.I. 12). Fully a year later, on June 23, 2014, Roxane moved this Court for leave to file a First Amended Answer, adding three new affirmative defenses: express license to the '122 and '216 Patents (Tenth Proposed Affirmative Defense), implied license to the '122 and '216 Patents (Eleventh Proposed Affirmative Defense), and an unclean clean hands defense (Twelfth Proposed Affirmative Defense). (D.I. 66.)

Roxane was aware of the facts on which its putative express and implied licenses are based at the time it filed its original answer and counterclaims. Besides being self-evident, this is confirmed by the fact that in August 2013, Roxane opposed Endo's motion for a preliminary injunction by arguing that Endo was not likely to succeed on the merits of its patent infringement claims because Roxane had an express or implied license to the patents-in-suit. Ex. A, Opposition of Roxane Laboratories, Inc. to Endo's Motion for Preliminary Injunction (Confined Solely to License Issue) (Corrected Version) (attached to the Declaration of Jonathan Loeb ("Loeb Decl.") filed herewith). Roxane submitted 15 pages of briefing directed solely to those licensing defenses. *Id.* The parties argued the license issues before this Court on September 12, 2013.

After this Court denied Endo's motion, Endo brought the licensing issue to the Federal Circuit. Roxane submitted a 34-page opposition (Loeb Decl. Ex. B), and on January 9, 2014, the parties presented their positions to the Federal Circuit at oral argument. The Federal Circuit rejected Roxane's license defenses as a matter of law. *See Endo Pharms. Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1374, 1376, 1379 (Fed. Cir. 2014).

Roxane now seeks to amend its complaint to add the same two affirmative defenses that the Federal Circuit has already rejected.

### **III. ARGUMENT**

A motion to amend a pleading should be denied when the amendment would be futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962). Ordinarily, an amendment to a pleading is futile when it cannot withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rule of Civil Procedure. *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001). Similarly, an amendment adding a new affirmative defense is futile when the defense cannot withstand a motion under Rule 12(f) of the Federal Rules of Civil Procedure. *Credit Suisse First Boston, LLC v. Intershop Commun. AG*, 407 F. Supp. 2d 541, 546 (S.D.N.Y. 2006). Rule 12(f) provides that a court may strike any “insufficient defense.” Fed. R. Civ. P. 12(f).

In view of the Federal Circuit’s decision rejecting Roxane’s license defenses as a matter of law, which decision is the law of the case and binding on this Court, Roxane’s attempt to assert those defenses via an amended answer would be futile. Accordingly, the Court should reject Roxane’s motion for leave to assert those defenses.

#### **A. THE FEDERAL CIRCUIT’S DECISION REJECTED ROXANE’S LICENSE DEFENSES AND HAS PRECLUSIVE EFFECT**

It is well-established that under the law of the case doctrine, if an appellate court has already decided an issue in a case, the trial court is required to follow the appellate court’s decision. *U.S. v. Quintieri*, 306 F.3d 1217, 1225 (2d Cir. 2002). Accordingly, an amendment is futile when the issue has already been decided by the appropriate court of review. *See, e.g., Pellegrini v. Analog Devices, Inc.*, 312 Fed. Appx. 304, 309 (Fed. Cir. 2008) (unpublished) (finding that a proposed amendment was futile, as it alleged infringement of products that the Federal Circuit had already found to be non-infringing).

Roxane argues that the Federal Circuit’s precedential decision rejecting Roxane’s license defenses as “meritless” is not binding on this Court because the decision was rendered in the context of vacating the denial of a motion for preliminary injunction. (D.I. 66 at 7-8.) While findings of fact and related conclusions of law made during a preliminary injunction hearing do not always constitute law of the case, and accordingly are not always binding at trial on the merits, this is not a hard and fast rule. *See, e.g., Intergraph Corp. v. Intel Corp.*, 253 F.3d 695, 699 (Fed. Cir. 2001) (finding that the Federal Circuit’s earlier conclusions of law made when vacating a preliminary injunction were the “law of the case”); *Intergraph Corporation v. Intel Corporation*, 195 F.3d 1346 (Fed. Cir. 1999) (vacating preliminary injunction). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The relevant question is not whether the Federal Circuit’s ruling was made in the context of a preliminary injunction — instead, the key consideration is whether the Federal Circuit’s legal conclusions concerning Roxane’s inadequate license defense are sufficiently final such that the “court sees no really good reason for permitting it to be litigated again.” *Lummus Co. v. Cmmw. Oil Refining Co.*, 297 F.2d 80, 89 (2d Cir. 1961); *see also Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1302-03 (Fed. Cir. 2012) (noting that due to the status of the case at that time, the Federal Circuit’s decision concerning claim construction at the



preliminary injunction stage may constitute the “law of the case.”); *Royal Ins. Co. of Am. v. Quinn-L Capital Corp.*, 3 F.3d 877, 881 (5th Cir. 1993) (finding that the court’s legal conclusions concerning jurisdiction, in response to an interlocutory appeal concerning a preliminary injunction, were the law of the case); *Miller Brewing Co. v. Joseph Schlitz Brewing Co.*, 605 F.2d 990, 995 (7th Cir. 1979) (“Although [a preliminary injunction] judgment will ordinarily not foreclose subsequent litigation on the merits, it will be given preclusive effect if it is necessarily based upon a determination that constitutes an insuperable obstacle to the plaintiff’s success on the merits.”).

When determining whether a court’s legal conclusions concerning a preliminary injunction are sufficiently definitive to preclude further litigation, courts can consider “the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review.” *Lummus Co.*, 297 F.2d at 89; *Amalgamated Sugar Co. v. NL Industries, Inc.*, 667 F. Supp. 87, 94 (S.D.N.Y. 1987) (giving preclusive effect to the district court’s finding of contract validity in a preliminary injunction decision, as under *Lummus*, the finding was a “final decision”); *AM Gen. Corp. v. DaimlerChrysler Corp.*, 246 F. Supp. 2d 1030, 1035-36 (N.D. Ind. 2003) (giving preclusive effect to the court’s contract interpretation at the preliminary injunction phase, as the interpretation was final). Here, the issue was heard at length, was actually reviewed — in detail — by the Federal Circuit, and the Federal Circuit’s decision was anything but tentative.

#### **B. ROXANE’S EXPRESS LICENSE DEFENSE IS FUTILE**

The Federal Circuit has already concluded *as a matter of law* that “Roxane’s express license arguments are meritless” (*Endo Pharms. Inc.*, 746 F.3d at 1374), and thus, granting Roxane leave to assert that defense would be futile.

The Federal Circuit specifically found that while Roxane holds a license to certain Endo patents, it does not have a license to the patents-in-suit: Roxane's license covers "any applications that claim priority to the '250 patent, including any continuation, continuation-in-part and divisional patent applications." *Id.* The license does not cover the '122 and '216 Patents at issue in this case because "[t]he '122 and '216 patents *do not* claim priority to the '250 patent." *Id.* (emphasis in original). The Federal Circuit further noted that the contract language concerning the scope of Roxane's license was "clear on its face." *Id.* Nothing about the Federal Circuit's decision was tentative. Instead, the Court was clear and definitive: the contract language is unambiguous and Roxane does not have an express license to practice the '122 and '216 patents. Roxane petitioned the Federal Circuit for rehearing *en banc*, but the Federal Circuit denied the petition. Loeb Decl. Ex. C, June 3, 2014 Denial of Rehearing En Banc.

No new facts or discovery could cause the court to ignore the established law of the case. Contract interpretation is a question of law. *See, e.g., Endo Pharms., Inc.*, 746 F.3d at 1374. The Federal Circuit found that the scope of Roxane's license is "clear on its face." *Id.* As Roxane itself argued to the Federal Circuit: "If a contract is 'clear and unambiguous on its face,' [the] court cannot 'consider parol evidence to interpret it or search for the parties' intent.'" Loeb Decl. Ex. B (*quoting Picture Patents, LLC v. Aeropostale, Inc.*, 788 F. Supp. 2d 127, 138 (S.D.N.Y. 2011)). Accordingly, no further factual development is necessary, and an amendment to add Roxane's "meritless" express license defense would be futile.

### **C. ROXANE'S IMPLIED LICENSE DEFENSE IS FUTILE**

The Federal Circuit similarly rejected Roxane's implied license defense. *Endo Pharms. Inc.*, 746 F.3d at 1379 ("You get what you bargain for. And we will not use the implied license doctrine to insert ourselves into that bargain and rewrite the contract."). The implied license defense Roxane seeks to raise is based on the same argument it made before the Federal Circuit.

*Compare* Roxane’s Proposed Amended Answer D.I. 67 Ex. 2 at 14 (“Under the terms of the settlement and license agreement, Endo provided Roxane a patent license and covenant not to sue regarding the product that was the subject of Roxane’s ANDA.”) with Loeb Decl. Ex. B, Roxane’s Appeal Brief at 26 (“The 2011 license granted Roxane the right to market its ANDA product.”).

The Federal Circuit has already analyzed the settlement agreement and determined that Roxane’s implied license argument fails as a matter of law. The Federal Circuit held that, under the clear terms of the settlement agreement, Roxane’s license was limited to specific patents, and not the Roxane ANDA product itself: Endo granted Roxane “a license and covenant not to sue limited to specific patents and patent applications. If [Roxane] wanted to market and sell [its] accused generic products free from any threat of being sued by Endo for patent infringement, [it] could have negotiated for the appropriate language in the settlement and license agreements.” *Endo Pharms. Inc.*, 746 F.3d at 1379. Instead, Roxane’s license is limited to specific enumerated patents and patents that “claim priority” to those enumerated patents. *Id.* at 1378. Moreover, the agreement included an express “No Implied Rights” provision stating unequivocally that Endo did not grant to Roxane any license or right “***whether by implication, estoppel or otherwise***, other than as expressly granted herein.” *Id.* at 1373 (emphasis added).

The Federal Circuit conclusively held that “[t]he lack of a continuation relationship between any of the asserted and licensed patents and explicit disclaimer of any other licenses not within the literal terms of the contract are dispositive.” *Id.* Thus, the terms of the license are clear, and Roxane cannot now argue that Endo granted it an implied license that is broader than the clear terms of the contract. As the Federal Circuit concluded, “[h]aving agreed to licenses

that do not cover the patents at issue in these appeals, [Roxane] will not now be heard to complain.” *Id.* at 1379.

The Federal Circuit further explained that Roxane’s implied license defense is an “invitation to expand the implied license doctrine.” In declining that invitation, the Federal Circuit explained: “You get what you bargain for. And we will not use the implied license doctrine to insert ourselves into that bargain and rewrite the contract.” *Id.* Even Judge Dyk, who dissented from the majority opinion with respect to Actavis’s implied license defense, agreed that Roxane does not have either an express or an implied license to the ’122 and ’216 patents. Indeed, he began his dissent by definitively stating: “I agree with the majority that Roxane did not have an express or implied license to practice the ’122 and ’216 patents.” *Id.*

Thus, the Federal Circuit has conclusively and definitively decided the issue based on the clear and unambiguous language of the parties’ agreement, and that ruling binds this Court. As a result, Roxane’s proposed amendment adding an implied license defense would be futile.

**D. ROXANE’S NEW ARGUMENTS CONTRADICT THE ARGUMENTS IT MADE TO THE FEDERAL CIRCUIT AND ARE NOT SUPPORTED BY ANY NEW RECORD EVIDENCE**

Before the Federal Circuit, Roxane argued that its contract was clear and unambiguous, and no parol evidence concerning license negotiations was necessary: “The negotiations leading to the 2011 license are irrelevant.” Loeb Decl. Ex. B at 27. In an attempt to revive the rejected license defenses, Roxane now apparently believes that parol evidence is essential, stating that: “Roxane’s motion is timely as it is based on information recently revealed during fact discovery, which is still ongoing.” (D.I. 66, Roxane Memo. at 3.)<sup>1</sup> Roxane’s argument is legally and

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<sup>1</sup> Endo does question the timeliness Roxane’s amendment with respect to the license defenses, as Roxane has clearly been aware of these defenses at least since its initial briefing on the issue — nine months ago.

factually misguided. The license was already construed as a matter of law by the Federal Circuit. While the Federal Circuit agreed with Roxane that the “language” of the license is “clear on its face,” the court found that the clear language favored Endo. *Endo Pharms. Inc.*, 746 F.3d at 1375. Accordingly, no parol evidence would alter the Federal Circuit’s decision.

Tellingly, Roxane fails to identify any newly discovered parol evidence that favors its position. The Federal Circuit noted that the parol evidence it reviewed was consistent with the plain language of the contract: “Although the language is clear on its face, the fact that Endo and Roxane considered including in their agreement a grant of a license to ‘an application *claiming a common priority date as* the licensed patents’ reinforces this conclusion.” *Endo Pharms. Inc.*, 746 F.3d at 1375. Roxane’s statement that the parol evidence before the Federal Circuit was “one-sided” and “incomplete” is irrelevant because even if there were contrary parol evidence — and Roxane points to none — that unidentified parol evidence (1) would not change the Federal Circuit’s legal conclusions relying on the plain meaning of the contract, (2) cannot override the fact that Endo expressly refused to provide a license to the patents-in-suit, and (3) cannot override the express “No Implied Rights” provision that the parties included in their agreement.

Moreover, Roxane’s failure to identify this alleged new parol evidence is inexcusable. At this point, fact discovery concerning the license issues has been going since at least August, 2013, Endo has responded to all of Roxane’s discovery requests on the issue, and Roxane has no further discovery pending. The only discovery that Roxane specifically mentions in its memorandum are two depositions that were completed by early March. Yet ***Roxane points to no specific evidence*** that was not before the Federal Circuit that it believes could change the outcome. Under these circumstances, Roxane’s statement that “a discussion of this evidence is premature in this motion for leave to amend” (D.I. 66, Roxane Memo. at 12) merely highlights

the vacuous nature of its assertions — if Roxane had evidence that should change the outcome, it undoubtedly would have featured that evidence front and center in its moving papers.<sup>2</sup>

#### **IV. CONCLUSION**

The parties have already extensively litigated Roxane's license defenses. The Federal Circuit decided the matter based on the clear and unambiguous language of the parties' agreement, and definitively and finally rejected the entirety of Roxane's positions as a matter of law. There is no new information that could change the Federal Circuit's holding and there is simply no good reason to re-litigate them. Accordingly, Endo respectfully requests that the Court deny Roxane's motion insofar as it seeks to add Roxane's Tenth Proposed Affirmative Defense (express license) and Eleventh Proposed Affirmative Defense (implied license).

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<sup>2</sup> It would be improper sandbagging for Roxane to identify additional allegedly relevant evidence for the first time in its Reply. *ABN Amro Verzekeringen BV v. Geologistics Americas, Inc.*, 485 F.3d 85, 97 n.12 (2d Cir. 2007) ("We decline to consider an argument raised for the first time in a reply brief.").

Respectfully submitted,

Dated: July 10, 2014

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 10, 2014, I served the foregoing **ENDO PHARMACEUTICALS INC'S OPPOSITION TO ROXANE'S MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER and DECLARATION OF JONATHAN D. LOEB IN SUPPORT OF ENDO PHARMACEUTICALS INC'S OPPOSITION TO ROXANE'S MOTION FOR LEAVE TO FILE A FIRST AMENDED ANSWER**, in unredacted form and with all Exhibits, on counsel for Roxane Laboratories, Inc. by email.

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